Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2016 Feb 16;164(4):279-96. [62 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2009 Nov 17;151(10):716-26, W-236.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendations and Evidence

The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. (B recommendation)

The decision to start screening mammography in women prior to age 50 years should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin biennial screening between the ages of 40 and 49 years. (C recommendation)

> For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 years. Of all of the age groups, women aged 60 to 69 years are most likely to avoid breast cancer death through mammography screening. While screening mammography in women aged 40 to 49 years may reduce the risk for breast cancer death, the

number of deaths averted is smaller than that in older women and the number of false-positive results and unnecessary biopsies is larger. The balance of benefits and harms is likely to improve as women move from their early to late 40s.

In addition to false-positive results and unnecessary biopsies, all women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to their health, or even apparent, during their lifetime (known as "overdiagnosis"). Beginning mammography screening at a younger age and screening more frequently may increase the risk for overdiagnosis and subsequent overtreatment.

Women with a parent, sibling, or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average-risk women from beginning screening in their 40s.

Go to the Clinical Considerations section for information on implementation of the C recommendation.

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women aged 75 years or older. (I statement)

The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer. (I statement)

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. (I statement)

These recommendations apply to asymptomatic women aged 40 years or older who do not have preexisting breast cancer or a previously diagnosed high risk breast lesion and who are not at high risk for breast cancer because of a known underlying genetic mutation (such as a *BRCA1* or *BRCA2* gene mutation or other familial breast cancer syndrome) or a history of chest radiation at a young age.

Clinical Considerations

Benefit of Screening

The results of the meta-analysis of clinical trials from the systematic evidence review commissioned by the USPSTF are summarized in Table 1 in the original guideline document. Over a 10-year period, screening 10,000 women aged 60 to 69 years will result in 21 (95% confidence interval [CI]) fewer breast cancer deaths. The benefit is smaller in younger women: Screening 10,000 women aged 50 to 59 years will result in 8 (CI) fewer breast cancer deaths, and screening 10,000 women aged 40 to 49 years will result in 3 (CI) fewer breast cancer deaths. Most of these trials began enrollment more than 30 years ago, and these estimates may not reflect the current likelihood of avoiding a breast cancer death with contemporary screening mammography technology. Mammography imaging has since improved, which may result in more tumors being detected at a curable stage today than at the time of these trials. However, breast cancer treatments have also improved, and as treatment improves, the advantage of earlier detection decreases, so that some of the women who died of breast cancer in the nonscreened groups in these trials would survive today.

Harms of Screening

The most important harm of screening is the detection and treatment of invasive and noninvasive cancer that would never have been detected, or threaten health, in the absence of screening (overdiagnosis and overtreatment). Existing science does not allow for the ability to determine precisely what proportion of cancer diagnosed by mammography today reflects overdiagnosis, and estimates vary widely depending on the data source and method of calculation used. In the United States, the rate of diagnosis of invasive plus noninvasive breast cancer increased by 50% during the era of mammography screening (see Figure 2 in the original guideline document). It is not possible to know with certainty what proportion of that increase is due to overdiagnosis and what proportion reflects other reasons for a rising incidence. If overdiagnosis is the only explanation for the increase, 1 in 3 women diagnosed with breast cancer today

is being treated for cancer that would never have been discovered or caused her health problems in the absence of screening. The best estimates from randomized controlled trials (RCTs) evaluating the effect of mammography screening on breast cancer mortality suggest that 1 in 5 women diagnosed with breast cancer over approximately 10 years will be overdiagnosed. Modeling studies conducted in support of this recommendation by the Cancer Intervention and Surveillance Modeling Network (CISNET) provide a range of estimates that reflect different underlying assumptions; the median estimate is that 1 in 8 women diagnosed with breast cancer with biennial screening from ages 50 to 75 years will be overdiagnosed. The rate increases with an earlier start age or with annual mammography. Even with the conservative estimate of 1 in 8 breast cancer cases being overdiagnosed, for every woman who avoids a death from breast cancer through screening, 2 to 3 women will be treated unnecessarily.

The other principal harms of screening are false-positive results, which require further imaging and often breast biopsy, and false-negative results. Table 2 in the original guideline document summarizes the rates of these harms per screening round using registry data for digital mammography from the Breast Cancer Surveillance Consortium (BCSC), a collaborative network of 5 mammography registries and 2 affiliated sites with linkages to tumor registries across the United States. (Note that Table 2 describes a different time horizon than Table 1 in the original guideline document [per screening round rather than per decade].)

When to Start Screening

Clinical trials, observational studies, and modeling studies all demonstrate that the likelihood of avoiding a breast cancer death with regular screening mammography increases with age, and this increase in benefit likely occurs gradually rather than abruptly at any particular age. In contrast, the harms of screening mammography either remain constant or decrease with age. For example, about the same number of breast biopsies are performed as a result of screening mammography in women aged 40 to 49 years as in those aged 60 to 69 years, but many more of these biopsies will result in a diagnosis of invasive cancer in the older age group. Thus, the balance of benefit and harms improves with age (see Table 3 in the original guideline document).

The USPSTF concludes that while there are harms of mammography, the benefit of screening mammography outweighs the harms by at least a moderate amount from age 50 to 74 years and is greatest for women in their 60s. For women in their 40s, the number who benefit from starting regular screening mammography is smaller and the number experiencing harm is larger compared with older women. For women in their 40s, the benefit still outweighs the harms, but to a smaller degree; this balance may therefore be more subject to individual values and preferences than it is in older women. Women in their 40s must weigh a very important but infrequent benefit (reduction in breast cancer deaths) against a group of meaningful and more common harms (overdiagnosis and overtreatment, unnecessary and sometimes invasive follow-up testing and psychological harms associated with false-positive test results, and false reassurance from false-negative test results). Women who value the possible benefit of screening mammography more than they value avoiding its harms can make an informed decision to begin screening.

Neither clinical trials nor models can precisely predict the potential benefits and harms that an individual woman can expect from beginning screening at age 40 rather than 50 years, as these data represent population effects. However, model results may be the easiest way for women to visualize the relative tradeoffs of beginning screening at age 40 versus 50 years. CISNET conducted modeling studies to predict the lifetime benefits and harms of screening with contemporary digital mammography at different starting and stopping ages and screening intervals. The models varied their assumptions about the natural history of invasive and noninvasive breast cancer and the effect of detection by digital mammography on survival. The models assumed the ideal circumstances of perfect adherence to screening and current best practices for therapy across the life span. Table 3 in the original guideline document compares the median and range across the models for predicted lifetime benefits and harms of screening biennially from ages 50 to 74 years with screening biennially from ages 40 to 74 years. (Note that Table 3 differs from Tables 1 and 2 in the original guideline document in terms of population metrics [per 1000 vs. 10,000 women] and time horizon considered [lifetime vs. 10-year or single event].)

It is, however, a false dichotomy to assume that the only options are to begin screening at age 40 or to wait until age 50 years. As women advance through their 40s, the incidence of breast cancer rises. The balance of benefit and harms may also shift accordingly over this decade, such that women in the latter half of the decade likely have a more favorable balance than women in the first half. Indeed, the CISNET models suggest that most of the benefit of screening women aged 40 to 49 years would be realized by starting screening at age 45.

Risk Factors That May Influence When to Start Screening

Advancing age is the most important risk factor for breast cancer in most women, but epidemiologic data from the BCSC suggest that having a first-degree relative with breast cancer is associated with an approximately 2-fold increased risk for breast cancer in women aged 40 to 49 years. Further, the CISNET models suggest that for women with about a 2-fold increased risk for breast cancer, starting annual digital screening at age 40 years results in a similar harm-to-benefit ratio (based on number of false-positive results or over diagnosed cases per 1000 breast cancer deaths avoided) as beginning biennial digital screening at age 50 years in average-risk women. This approach has not been formally tested in a clinical trial; therefore, there is no direct evidence that it would result in net benefit similar to that of women aged 50 to 74 years. However, given the increased burden of disease and potential likelihood of benefit, women aged 40 to 49 years who have a known first-degree relative (parent, child, or sibling) with breast cancer may consider initiating screening earlier than age 50 years. Many other risk factors have been associated with breast cancer in epidemiologic studies, but most of these relationships are weak or inconsistent and would not likely influence how women value the tradeoffs of the potential benefits and harms of screening. Risk calculators, such as the National Cancer Institute's Breast Cancer Risk Assessment Tool (available at www.cancer.gov/BCRISKTOOL), have good calibration between predicted and actual outcomes in groups of women but are not accurate at predicting an individual woman's risk for breast cancer.

How Often to Screen

Once a woman has decided to begin screening, the next decision is how often to undergo screening. No clinical trials compared annual mammography with a longer interval in women of any age. In the randomized trials that demonstrated the effectiveness of mammography in reducing breast cancer deaths in women aged 40 to 74 years, screening intervals ranged from 12 to 33 months. There was no clear trend for greater benefit in trials of annual mammography, but other differences between the trials preclude certainty that no difference in benefit exists. Available observational evidence evaluating the effects of varying mammography intervals found no difference in the number of breast cancer deaths between women aged 50 years or older who were screened biennially versus annually.

Regardless of the starting age for screening, the models consistently predict a small incremental increase in the number of breast cancer deaths averted when moving from biennial to annual mammography, but also a large increase in the number of harms (see Table 4 in the original guideline document). The USPSTF concludes that for most women, biennial mammography screening provides the best overall balance of benefit and harms.

When to Consider Stopping Screening

Clinical trial data for women aged 70 to 74 years are inconclusive. In its 2009 recommendation, the USPSTF extended the recommendation for screening mammography to age 74 years based on the extrapolation that much of the benefit seen in women aged 60 to 69 years should continue in this age range, and modeling done at the time supported this assumption. Current CISNET models suggest that women aged 70 to 74 years with moderate to severe comorbid conditions that negatively affect their life expectancy are unlikely to benefit from mammography. Moderate comorbid conditions include cardiovascular disease, paralysis, and diabetes. Severe comorbid conditions include (but are not limited to) acquired immune deficiency syndrome (AIDS), chronic obstructive pulmonary disease, liver disease, chronic renal failure, dementia, congestive heart failure, and combinations of moderate comorbid conditions, as well as myocardial infarction, ulcer, and rheumatologic disease.

Screening in Women Aged 75 Years or Older

The USPSTF found insufficient evidence to assess the balance of benefits and harms of screening mammography in women aged 75 years or older. CISNET models suggest that biennial mammography screening may potentially continue to offer a net benefit after age 74 years among those with no or low comorbidity, but no randomized trials of screening included women in this age group.

DBT as a Primary Screening Strategy

The USPSTF found insufficient evidence to assess the balance of benefits and harms of DBT as a primary screening method for breast cancer.

See the original guideline document for additional information on DBT as a primary screening strategy, including potential benefits and harms.

Primary and Adjunctive Screening in Women With Dense Breasts

The USPSTF found insufficient evidence to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, MRI, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.

See the original guideline document for additional information on DBT as a primary screening strategy, including potential benefits and harms.

Other Approaches to Prevention

The USPSTF has made recommendations about the use of medications to reduce women's risk for breast cancer, as well as risk assessment, genetic counseling, and genetic testing for *BRCA1*- or *BRCA2*-related cancer (including breast cancer). These recommendations are available on the USPSTF Web site (www.uspreventiveservicestaskforce.org).

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: The number, size, or quality of individual studies Inconsistency of findings across individual studies Limited generalizability of findings to routine primary care practice Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: The limited number or size of studies Important flaws in study design or methods Inconsistency of findings across individual studies Gaps in the chain of evidence Findings not generalizable to routine primary care practice A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Internal Medicine

Nursing

Obstetrics and Gynecology

Oncology

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting scientific evidence on screening for breast cancer

Target Population

Asymptomatic women aged 40 years or older who do not have preexisting breast cancer or a previously diagnosed high-risk breast lesion and who are not at high risk for breast cancer because of a known underlying genetic mutation (such as a *BRCA1* or *BRCA2* gene mutation or other familial breast cancer syndrome) or a history of chest radiation at a young age

Interventions and Practices Considered

1. Biennial screening mammography (women aged 50-74 years)
2. Digital breast tomosynthesis (DBT) (not recommended)
3. Adjunctive screening (not recommended)
    - Breast ultrasonography
    - Magnetic resonance imaging (MRI)

Major Outcomes Considered

Effectiveness of Breast Cancer Screening: Systematic Review and Meta-analysis to Update the 2009 U.S. Preventive Services Task Force Recommendation

> Key Question 1: What is the effectiveness of routine mammography screening in reducing breast cancer–specific and all-cause mortality, and how does it differ by age, risk factor, and screening interval?
> Key Question 2: What is the effectiveness of routine mammography screening in reducing the incidence of advanced breast cancer and treatment-related morbidity, and how does it differ by age, risk factors, and screening interval?
> Key Question 3: How does the effectiveness of routine breast cancer screening in reducing breast cancer–specific and all-cause mortality vary by different screening modality?

Key Question 4: How does the effectiveness of routine breast cancer screening in reducing the incidence of advanced breast cancer and treatment-related morbidity vary by different screening modality?

Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force

Key Question 1: What are the accuracy and reproducibility of Breast Imaging Reporting and Data System (BI-RADS) determination of breast density?
Key Question 2: What are the test performance characteristics of newer technologies for breast cancer screening when used as supplemental tests after a negative screening mammogram in women found to have dense breasts, and how do these performance characteristics differ by age and risk factors?
Key Question 3: When performed after a negative screening mammogram in women found to have dense breasts, what is the effectiveness of supplemental screening with breast ultrasonography, MRI, or breast tomosynthesis on proximate clinical outcomes, including cancer detection rates, DCIS detection rates, stage at diagnosis, recall rates, biopsy rates, and interval cancer rates?
Key Question 4: What are the harms associated with being identified as having dense breasts, including psychological and quality-of-life impacts and harms associated with supplemental screening evaluation, including evaluation of false-positive results?

Harms of Breast Cancer Screening: Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation

Key Question 1: What are the harms of routine mammography screening, and how do they differ by age, risk factors, and screening interval?
Key Question 2: How do the harms of routine breast cancer screening vary by different screening modality?

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Pacific Northwest Evidence-based Practice Center (EPC), Center for Healthcare Policy and Research, University of California Davis, Sacramento, and the Kaiser Permanente Research Affiliates EPC for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Effectiveness of Breast Cancer Screening: Systematic Review and Meta-analysis to Update the 2009 U.S. Preventive Services Task Force Recommendation

Data Sources and Searches

A research librarian conducted electronic database searches of the Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Ovid MEDLINE to 4 June 2015. Searches were supplemented by references identified from additional sources, including reference lists and experts. Additional unpublished data were provided by the investigators of the Canadian National Breast Screening

Study (CNBSS) and Swedish Two-County Trial.

Study Selection

Two investigators independently evaluated each study to determine inclusion eligibility on the basis of prespecified criteria. Discrepancies were resolved through consensus.

The EPC investigators included randomized controlled trials (RCTs); observational studies of screening cohorts; and systematic reviews that compared outcomes of women exposed to screening versus not screening. For advanced cancer outcomes, studies that reported the incidence of late-stage disease among screened and unscreened populations were included, whereas those reporting comparisons of detection methods that did not capture a woman's longitudinal screening experience were not included (e.g., rates of screen-detected vs. non–screen detected cancer).

Studies providing outcomes specific to age, risk factors, screening intervals, and modalities were preferred over studies providing general outcomes, when available. Studies most clinically relevant to practice in the United States were selected over studies that were less relevant. Relevance was determined by practice setting, population, date of publication, and use of technologies and therapies in current practice. Studies meeting criteria for high quality and those with designs ranked higher in the study design–based hierarchy of evidence were emphasized because they are less susceptible to bias (e.g., RCTs over observational studies).

Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force

Data Sources and Searches

MEDLINE, PubMed, EMBASE, and the Cochrane Library were searched for relevant English-language studies published between January 2000 and July 2015. The EPC investigators reviewed reference lists from retrieved articles and references suggested by experts.

Study Selection

Two investigators independently reviewed abstracts and full-text articles for inclusion according to predetermined criteria. Included studies examining the reproducibility of Breast Imaging Reporting and Data System (BI-RADS) breast density categorization focused on asymptomatic women aged 40 years or older undergoing digital or film mammography. Included studies on supplemental screening with hand-held breast ultrasound (HHUS), automated whole-breast ultrasonography (ABUS), magnetic resonance imaging (MRI), or digital breast tomosynthesis (DBT) reported outcomes for asymptomatic women with dense breasts aged 40 years and older. In studies that focused primarily on women at high risk for breast cancer (including those with preexisting breast cancer or high-risk breast lesions [such as ductal carcinoma in situ, atypical hyperplasia, and lobular carcinoma in situ], *BRCA* mutations, familial breast cancer syndromes, or previous chest-wall radiation) and studies that included women with nondense breasts, the EPC investigators analyzed the relevant subset when available in the publication or provided by the authors.

A priori inclusion criteria limited studies on BI-RADS reproducibility to fair- or good-quality RCTs; cohort studies; or test sets involving multiple blind readings by at least 3 readers. Studies on test performance characteristics and outcomes of supplemental screening modalities were limited to fair- or good-quality RCTs; cohort studies; or diagnostic accuracy studies with reference standards applied to all participants. The EPC investigators examined sensitivity, specificity, positive predictive values (PPVs), negative predictive values (NPVs), and available clinical outcomes (including cancer detection rates, recall rates, and biopsy rates). They defined recall as the need for any additional diagnostic testing after supplemental screening, including imaging and biopsy.

Harms of Breast Cancer Screening: Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation

Data Sources and Searches

A research librarian conducted electronic searches of the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and Ovid MEDLINE through December 2014 for relevant studies and systematic reviews. Searches were supplemented by references identified from additional sources, including reference lists and experts. Studies of harms included in the previous systematic review for the USPSTF were also included.

Study Selection

Two investigators independently evaluated each study to determine eligibility based on prespecified inclusion criteria. Discrepancies were resolved through consensus.

The EPC investigators included recently published systematic reviews; RCTs; and observational studies of prespecified harms. When available, studies providing outcomes specific to age, risk factors, screening intervals, and screening modalities were preferred over studies providing general outcomes. Studies that were most clinically relevant to practice in the United States were selected; relevance was determined by practice setting, population, date of publication, and use of technologies and therapies in current practice. Studies meeting criteria for high quality and with designs ranked higher in the study design–based hierarchy of evidence were emphasized because they are less susceptible to bias (for example, RCTs were chosen over observational studies).

Number of Source Documents

Effectiveness of Breast Cancer Screening: Systematic Review and Meta-analysis to Update the 2009 U.S. Preventive Services Task Force Recommendation

Of the 12,070 abstracts identified by electronic searches and other sources, 38 studies met inclusion criteria for key questions in this report, including 5 systematic reviews of 62 studies. See Appendix Figure 2 in the systematic review (see the "Availability of Companion Documents" field).

Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force

The literature search yielded 2067 unique citations; 128 full-text articles considered potentially relevant were reviewed to identify 24 unique studies meeting inclusion criteria (see Appendix Figure 2 [see the "Availability of Companion Documents" field]). Table 1 in the systematic review provides the characteristics of included studies. No studies addressed the effect of supplemental screening (compared with women without supplemental screening) on breast cancer morbidity or mortality.

Harms of Breast Cancer Screening: Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation

Of the 12,004 abstracts identified by searches and other sources, 59 studies met inclusion criteria for key questions in this report, including 10 systematic reviews of 134 studies and 49 additional studies. See Appendix Figure 2 in the systematic review (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Two investigators independently applied criteria developed by the U.S. Preventive Services Task Force (USPSTF) to rate the quality of each study as good, fair, or poor for studies designed as randomized control trials (RCTs), cohort studies, case-control studies, and systematic reviews. Criteria to rate studies with other designs included in the reviews are not available. See the "Description of the Methods Used to

Analyze the Evidence" field for further information.

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Pacific Northwest Evidence-based Practice Center (EPC), Center for Healthcare Policy and Research, University of California Davis, Sacramento, and the Kaiser Permanente Research Affiliates EPC for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Effectiveness of Breast Cancer Screening: Systematic Review and Meta-analysis to Update the 2009 U.S. Preventive Services Task Force Recommendation

Data Extraction and Quality Assessment

Details of the study design, patient population, setting, screening method, interventions, analysis, follow-up, and results were abstracted by one investigator and confirmed by a second. Two investigators independently applied criteria developed by the USPSTF to rate the quality of each study as good, fair, or poor for studies designed as randomized controlled trials (RCTs), cohort studies, case–control studies, and systematic reviews; criteria to rate other study designs included in this review are not available. Discrepancies were resolved through consensus.

Data Synthesis

The EPC investigators conducted several meta-analyses to determine more precise summary estimates when adequate data were reported by trials rated as fair- or good-quality. In each meta-analysis, the number of included trials was counted as the number of discrete data sources contributing to the summary estimate using their most recent results. To determine the appropriateness of meta-analysis, the EPC investigators considered clinical and methodological diversity and assessed statistical heterogeneity. All outcomes were binary (breast cancer mortality, all-cause mortality, and advanced cancer incidence defined by stage and tumor size). The EPC investigators used a random effects model to combine relative risks (RRs) as the effect measure of the meta-analyses, while incorporating variation among studies. A profile-likelihood model was used to combine studies in the primary analyses. The EPC investigators assessed the presence of statistical heterogeneity among the studies by using the standard Cochran chi-square test, and the magnitude of heterogeneity by using the I^2 statistic.

To account for clinical heterogeneity and obtain clinically meaningful estimates, the EPC investigators stratified the analyses by age group whenever possible (39 to 49 years, 50 to 59 years, 60 to 69 years, 70 to 74 years, and ≥50 years). They obtained additional age-stratified data for the meta-analysis from the investigators of 3 trials (Tabár L, personal communication).

For breast cancer mortality, the EPC investigators used 2 methods of including cases to help clarify discrepancies between estimates. The long case accrual method counts all breast cancer cases contributing to breast cancer deaths. In this method, the case accrual time is equivalent to or close to the follow-up time. The short case accrual method includes only deaths that occur among cases of breast cancer diagnosed during the screening intervention period, and in some trials, within an additional defined case accrual period. The longest follow-up times available for each trial were selected for inclusion in the initial meta-analyses, and sensitivity analyses were conducted by using results of short case accrual methods.

The EPC investigators calculated the absolute rate reduction for 100,000 woman-years of follow-up (i.e., 10,000 women followed for 10 years) for each age group on the basis of the combined RR and the combined cancer rate of the control group. EPC investigators estimated combined cancer rates for each age group for controls with a random effects Poisson model using data from the trials. All analyses were performed by using Stata/IC, version 13.1 (StataCorp).

EPC investigators assessed the aggregate internal validity (quality) of the body of evidence for each key question as good, fair, or poor by using methods developed by the USPSTF that are based on the number, quality, and size of studies; consistency of results between studies; and directness of evidence.

Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force

Data Extraction and Quality Assessment

Two investigators critically appraised all included studies independently using the U.S. Preventive Services Task Force's (USPSTF's) design-specific criteria, supplemented with the National Institute for Health and Clinical Excellence methodology checklists and the Quality Appraisal Tool for Studies of Diagnostic Reliability. According to USPSTF criteria, a good-quality study generally met all prespecified criteria; fair-quality studies did not meet all criteria but had no important limitations. Poor-quality studies had important limitations that could invalidate results (inadequate or biased application of reference standard; population limited to very high-risk patients).

Data Synthesis and Analysis

When available or provided by the authors, results of supplemental screening for subgroups of women with dense breasts were extracted; the EPC investigators excluded those with other risk factors for breast cancer. They calculated the sensitivity and specificity of the supplemental breast screening tests for women with negative mammography results. Only cancers detected by the supplemental test after negative mammography results and cancers found at interval follow-up were included. Hence, the values reported represent the sensitivity and specificity for detection of additional cancer in women with negative mammography findings. Similarly, the EPC investigators defined cancer detection rates, recall rates, and biopsy rates to include only those cancer cases, recalls, and biopsies related to supplemental screening after negative results on mammography. Meta-analysis was not performed because there were few good quality studies.

Harms of Breast Cancer Screening: Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation

Data Extraction and Quality Assessment

Details of the study design, patient population, setting, screening method, interventions, analysis, follow-up, and results were abstracted by one investigator and confirmed by another. Two investigators independently applied criteria developed by the USPSTF to rate the quality of each RCT, cohort study, case–control study, and systematic review as good, fair, or poor; criteria to rate studies with other designs included in this review are not available. Discrepancies were resolved through consensus.

Data Synthesis

Studies meeting inclusion criteria were qualitatively synthesized. Most studies in this review had designs for which quality rating criteria are not available, which limited data synthesis. When possible, the EPC investigators assessed the aggregate internal validity (quality) of the body of evidence for each key question (good, fair, or poor) by using methods developed by the USPSTF based on the number, quality, and size of studies; consistency of results between studies; and directness of evidence.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

> Do the studies have the appropriate research design to answer the key question(s)?
> To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
> To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
> How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
> How consistent are the results of the studies?
> Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers (EPCs) to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205. www.annals.org .

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient

evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: The number, size, or quality of individual studies Inconsistency of findings across individual studies Limited generalizability of findings to routine primary care practice Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: The limited number or size of studies Important flaws in study design or methods Inconsistency of findings across individual studies Gaps in the chain of evidence Findings not generalizable to routine primary care practice A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in this assessment.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment

A draft recommendation statement was posted for public comment on the USPSTF Web site from 21 April through 18 May 2015. In response to the comments received, the USPSTF clarified certain terminology (for example, digital breast tomosynthesis [DBT] and misdiagnosis vs. overdiagnosis), updated or added references (for example, those related to the long-term outcomes of ductal carcinoma in situ [DCIS]), and provided additional context around the potential risks of radiation exposure due to mammography screening.

See the original guideline document for a full discussion of the USPSTF response to public comment.

Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the American College of Radiology; the American Congress of Obstetricians and Gynecologists; the American Cancer Society; the American College of Physicians; the American Academy of Family Physicians; the Canadian Task Force on Preventive Health Care; national breast cancer screening programs in the United Kingdom, the Netherlands, Switzerland, Poland, Norway, Luxembourg, Germany, Finland, Denmark, and Belgium; and the International Agency for Research on Cancer.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefit of Screening and Early Treatment

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that mammography screening reduces breast cancer mortality in women aged 40 to 74 years. The number of breast cancer deaths averted increases with age; women aged 40 to 49 years benefit the least and women aged 60 to 69 years benefit the most. Age is the most important risk factor for breast cancer, and the increased benefit observed with age is at least partly due to the increase in risk. Women aged 40 to 49 years who have a first degree relative with breast cancer have a risk for breast cancer similar to that of women aged 50 to 59 years without a family history. Direct evidence about the benefits of screening mammography in women aged 75 years or older is lacking.

The USPSTF found inadequate evidence on the benefits of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer. Similarly, the USPSTF found inadequate evidence on the benefits of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. In both cases, while there is some information about the accuracy of these methods, there is no information on the effects of their use on health outcomes, such as breast cancer incidence, mortality, or overdiagnosis rates.

Potential Harms

Harms of Screening and Early Treatment

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that screening for breast cancer with mammography results in harms for women aged 40 to 74 years. The most important harm is the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to a woman's health, or even apparent, during her lifetime (that is, overdiagnosis and overtreatment). False-positive results are common and lead to unnecessary and sometimes invasive follow-up testing, with the potential for psychological harms (such as anxiety). False-negative results (that is, missed cancer) also occur and may provide false reassurance. Radiation-induced breast cancer and resulting death can also occur, although the number of both of these events is predicted to be low.

The USPSTF found inadequate evidence on the harms of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer. Similarly, the USPSTF found inadequate evidence on the harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. In both cases, while there is some information about the accuracy of these methods, there is no information on the effects of their use on health outcomes, such as breast cancer incidence, mortality, or overdiagnosis rates.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without obvious related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2016 Feb 16;164(4):279-96. [62 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Feb 16

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

Composition of Group That Authored the Guideline

*Task Force Members**: Albert L. Siu, MD, MSPH (*Chair*) (Mount Sinai School of Medicine, New York, and James J. Peters Veterans Affairs Medical Center, Bronx, New York); Kirsten Bibbins-Domingo, PhD, MD, MAS (*Co-Vice Chair*) (University of California, San Francisco, San Francisco, California); David C. Grossman, MD, MPH (*Co-Vice Chair*) (Group Health Research Institute, Seattle, Washington); Linda Ciofu Baumann, PhD, RN, APRN (University of Wisconsin, Madison, Wisconsin); Karina W. Davidson, PhD, MASc (Columbia University, New York, New York); Mark Ebell, MD, MS (University of Georgia, Athens, Georgia); Francisco A.R. García, MD, MPH (Pima County Department of Health, Tucson, Arizona); Matthew Gillman, MD, SM (Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts); Jessica Herzstein, MD, MPH (Independent Consultant, Washington, DC); Alex R. Kemper, MD, MPH, MS (Duke University, Durham, North Carolina); Alex H. Krist, MD, MPH (Fairfax Family Practice, Fairfax, and Virginia Commonwealth University, Richmond, Virginia); Ann E. Kurth, PhD, RN, MSN, MPH (New York University, New York, New York); Douglas K. Owens, MD, MS (Veterans Affairs Palo Alto Health Care System, Palo Alto, and Stanford University, Stanford, California); William R. Phillips, MD, MPH (University of Washington, Seattle, Washington); Maureen G. Phipps, MD, MPH (Brown University, Providence, Rhode Island); and Michael P. Pignone, MD, MPH (University of North Carolina, Chapel Hill, North Carolina). Michael LeFevre, MD, MSPH, Immediate Past Chair (University of Missouri, Columbia, Missouri), also contributed to the development of this recommendation.

*Members of the U.S. Preventive Services Task Force (USPSTF) at the time this recommendation was finalized. For a list of current Task Force members, go to http://www.uspreventiveservicestaskforce.org/Page/Name/our-members .

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2009 Nov 17;151(10):716-26, W-236.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Annals of the Internal Medicine Web site .

Availability of Companion Documents

The following are available:

Evidence Reviews:

Nelson HD, Cantor A, Humphrey L, Fu R, Pappas M, Daeges M, Griffin J. Screening for breast cancer: a systematic review to update the 2009 U.S. Preventive Services Task Force recommendation, Evidence Synthesis No. 124. AHRQ Publication No. 14-05201-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2016 Jan. 286 p.

Nelson HD, Fu R, Cantor A, Pappas M, Daeges M, Humphrey L. Effectiveness of breast cancer screening: systematic review and meta-analysis to update the 2009 U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2016 Feb 16;164(4):244-55.

Nelson HD, O'Meara ES, Kerlikowske K, Balch S, Miglioretti D. Factors associated with rates of false-positive and false-negative results from digital mammography screening: an analysis of registry data. Ann Intern Med. 2016 Feb 16;164(4):226-35.

Nelson HD, Pappas M, Cantor A, Griffin J, Daeges M, Humphrey L. Harms of breast cancer screening: systematic review to update the 2009 U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2016 Feb 16;164(4):256-67.

Melnikow J, Fenton JJ, Miglioretti D, Whitlock EP, Weyrich MS. Screening for breast cancer with digital breast tomosynthesis. Evidence Synthesis No. 125. AHRQ Publication No. 14-05201-EF-2. Rockville (MD): Agency for Healthcare Research and Quality; 2016 Jan. 19 p.

Melnikow J, Fenton JJ, Whitlock EP, Miglioretti DL, Weyrich MS, Thompson JH, Shah K. Supplemental screening for breast cancer in women with dense breasts: a systematic review for the U.S. Preventive Service Task Force, Evidence Synthesis No. 126. AHRQ Publication No. 14-05201-EF-3. Rockville (MD): Agency for Healthcare Research and Quality; 2016 Jan. 101 p.

Melnikow J, Fenton JJ, Whitlock EP, Miglioretti DL, Weyrich MS, Thompson JH, Shah K. Supplemental screening for breast cancer in women with dense breasts: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2016 Feb 16;164(4):268-78.

Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

Modeling Reports:

Mandelblatt JS, Stout NK, Schechter CB, van den Broek JJ, Miglioretti DL, Krapcho M, et al. Collaborative modeling of the benefits and harms associated with different U.S. breast cancer

screening strategies. Ann Intern Med. 2016 Feb 16;164(4):215-25.
Miglioretti DL, Lange J, van den Broek JJ, Lee CI, van Ravesteyn NT, Ritley D, et al. Radiation-induced breast cancer incidence and mortality from digital mammography screening: a modeling study. Ann Intern Med. 2016 Feb 16;164(4):205-14.

Available from the USPSTF Web site .

Background Articles:

Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:123-7.
Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med 2007;147:117-22.
Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med 2007;147:871-5.
Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Available from the USPSTF Web site .

The following are also available:

Primary screening for breast cancer with conventional mammography: clinical summary. Rockville (MD): U.S. Preventive Services Task Force. 2016 Feb. 2 p. Available from the USPSTF Web site .

The guide to clinical preventive services, 2014. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014. 144 p. Available from the AHRQ Web site .

Additional resources, including an editorial are available from the USPSTF Web site .

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

The following are available:

Screening for breast cancer. Understanding task force recommendations. Rockville (MD): U.S. Preventive Services Task Force; 2016 Jan. 6 p. Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

Screening for breast cancer: recommendations from the U.S. Preventive Services Task Force. Summaries for patients. Ann Intern Med. 2016 Feb 16;164(4):I-28. Available from the Annals of Internal Medicine Web site .

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov .

NGC Status

This NGC summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. The summary was updated by ECRI on March 6, 2002. The updated information was verified by the guideline developer as of March 8, 2002. This summary was updated on September 4, 2002. This summary was updated by ECRI Institute on November 23, 2009. The information was verified by the guideline developer on December 30, 2009. This summary was updated to reflect the information in the addendum on January 8, 2010. This summary was updated again by ECRI Institute on March 15, 2016. The updated information was verified by the guideline developer on March 30, 2016.

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